REMARKS

Initially, it is noted that the Examiner has indicated that claims 24 and 26 have been allowed. In addition, the Examiner has objected to claim 30 as lacking a period. Applicant has amended claim 30 to add the period, and as such, withdrawal of the Examiner's objection of claim 30 is respectfully requested.

Claims 21, 27, 29 and 30 have been rejected under 35 USC §103(a) as being unpatentable over newly cited Gross et al., U.S. Patent 5,848,991 in view of newly cited Richelsoph, U.S. Patent 5,466,261, and further in view of Ziaie et al., U.S. Patent Publication 2004/0248326. As hereinafter described, Applicant respectfully disagrees with the Examiner's basis for the rejection and requests reconsideration in view of the following comments.

Claim 21 defines a microfluidic device for delivering a drug to an individual. The device includes a body defining a chamber having a fluid impermeable boundary and including a membrane for defining a reservoir. The membrane isolates the reservoir from the chamber. An output needle has an input in communication with the reservoir and an output receivable within the individual. An aqueous solution is selectively deposited into the chamber of the body through the fluid impermeable boundary. An adhesive is provided for affixing the body to the individual. A pressure source including a hydrogel member is received within the chamber. The hydrogel member is expandable in response to communication to the aqueous solution being deposited in the chamber. The hydrogel member is engageable with the reservoir and urges the drug from the reservoir through the output needle as the hydrogel member expands. A valve interconnects the reservoir and the output needle. The valve is movable between a non-actuated position wherein the valve prevents the flow of the drug from the reservoir to the output needle and an actuated position wherein the valve allows for the flow of the drug from the reservoir to the output needle. As hereinafter described, none of the cited references show or suggest a microfluidic device for delivering a drug to an individual that incorporates an aqueous solution that is selectively deposited into the chamber of a body through a fluid impermeable boundary wherein a

hydrogel member within the chamber acts as a constant pressure source to urge the drug from a reservoir.

The Gross et al., '991 patent discloses an intradermal drug delivery device including housing 2 incorporating a deformable liquid-impermeable membrane 8 and a rigid liquid-permeable membrane 40. One side of the impermeable membrane 8 and housing section 2a define drug reservoir 10. The other side of membrane 8 defines, with one side of the rigid liquid permeable membrane 40, a saline chamber 42. The other side of the permeable membrane 40 and housing section 2b define pure water chamber 44. Saline chamber 42 may be filled via injection plug 46 and pure water chamber 44 may be filled via injection plug 48. When the three chambers 10, 42 and 44 are filled as described above, water from chamber 44 will permeate by osmosis through membrane 40 into the saline chamber 42, thereby expanding that chamber and contracting the drug reservoir 10, forcing the drug out through the hollow needle 14. Hence, the pressure source (namely, a hydrogel member) is not positioned in a chamber having a fluid impermeable boundary as required by claim 21. In the '991 patent, water clearly passes through permeable membrane 40. The Richelsoph '261 patent and the Ziaie et al., '326 publication cannot cure the deficiencies of the '911 patent.

The '261 patent discloses an adjustable length prosthetic implant includes a stem having a rod portion, the rod portion including a first end portion adapted for connection to a bone and a second end portion including a piston reciprocable in a sleeve. The sleeve includes a closed end and an inner chamber extending to an opposite open end and defining an axial dimension. The chamber contains the piston for sliding movement therethrough and extension of the first end portion of the stem from the open end of the sleeve. The closed end of the sleeve includes an outer surface having a mounting component thereon for mounting on a bone. An inner surface of the closed end cooperates with the piston to define an axially expandable pocket therebetween. Hydrogel is disposed within the pocket and is axially expandable relative to the axis defined by the chamber upon contact with fluid for to incrementally extending the stem from the open end of the sleeve to adjust the length of prosthetic implant. Hence, unlike independent claim 21 wherein hydrogel member within the chamber acts as a constant pressure source to urge the drug from a reservoir, the hydrogel in the implant of the '261 patent acts merely to adjust the length of the piston extending from the sleeve and to prevent the piston from retracting back into the sleeve of the implant. There

is no teaching or suggestion in the '261 patent to utilize a hydrogel as a constant pressure source. In fact, constant pressure urging the piston from the sleeve of the implant would render the implant disclosed in the '261 patent inoperable for its intended purpose, namely, providing a prostheses of proper length for a skeletal joint in a juvenile patient. Consequently, there is no teaching or suggestion for the Examiner's suggested combination.

The '326 application discloses a plurality of hydrogel actuated devices that are used for controlled drug delivery either in response to a predetermined stimulus or for pulsating delivery. While the device does incorporate a hydrogel responsive valve between drug reservoir and the output needle as suggested by the Examiner, it must be noted that the device is implantable such that actuation of the hydrogel is accomplished by diffusion of the aqueous solution thorough a porous membrane. Hence, the hydrogel is not received in a chamber having a fluid impermeable boundary as required by independent claim 21. Further, there is no suggestion or teaching in the '326 application to provide a microfluidic device for delivering drugs that incorporates an aqueous solution that is selectively deposited into the chamber of the body through the fluid impermeable boundary wherein a hydrogel member expands in response to exposure to the aqueous solution selectively deposited in the chamber. Clearly, since the aqueous solution passes through a porous membrane, there would be no incentive or purpose to modify the device disclosed in the '326 application to provide for the aqueous solution to be selectively deposited into a fluid impermeable chamber housing the hydrogel.

In view of the foregoing, it is believed that independent claim 21 defines over the cited references and is in proper form for allowance. Claim 29 depends from independent claim 21 and further defines a device not shown or suggested in the art. It is believed that claim 29 is allowable as depending from an allowable base claim and in view of the subject matter of the claim.

Claim 27 defines a microfluidic device for delivering a drug to an individual. The microfluidic device includes a body defining a chamber having a fluid impermeable boundary for receiving an aqueous solution therein and including a membrane for defining a reservoir. The membrane isolates the reservoir from the chamber. An output needle has an input in communication with the reservoir and an output receivable within the individual. The

aqueous solution having a predetermined condition is selectively deposited into the chamber of the body. An adhesive is provided for affixing the body to the individual. A pressure source including a hydrogel member is received in the chamber and is expandable in response to exposure to the aqueous solution having the predetermined condition injected into the chamber. The hydrogel member engages the reservoir and urges the drug from the reservoir through the output needle as the hydrogel member expands. A valve interconnects the reservoir and the output needle. The valve is movable between a non-actuated position when the valve prevents the flow of drug from the reservoir to the output needle and an actuated position when the valve allows for the flow of the drug to the reservoir to the output needle.

Similar to claim 21, claim 27 defines a microfluidic device including an aqueous solution that is selectively deposited into a chamber of a body having a fluid impermeable boundary wherein a hydrogel member acts as a pressure source to engage the reservoir and urge the drug from the reservoir. As heretofore described, none of the cited references show or suggest such a structure. Consequently, it is believed that independent claim 27 defines over the cited references and is in proper form for allowance. Claim 30 depends from independent claim 27 and further defines a device not shown or suggested in the art. It is believed that claim 30 is allowable as depending from an allowable base claim and in view of the subject matter of the claim.

In view of the foregoing, Applicant believes that the present application with claims 21, 24, 26-27, and 29-30 is in proper form for allowance and such action is earnestly solicited. The Director is hereby authorized to charge payment of any other fees associated with this communication or credit any overpayment to Deposit Account No. 50-1170.

Respectfully submitted,

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